



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 24 1998

Josette Decaux
President
Catalysis, S.L.
Zurbano, 39
E-28010 Madrid
SPAIN

Dear Sir/Madam:

This is in response to your letter of September 1, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Catalysis, S.L. is making the following claim for the product "DIAMEL:"

"DIAMEL provides the necessary nutrients that complement and enrich the diet of diabetic patients."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely diabetes. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of any assistance

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Florida District Office, Office of Compliance, HFR-SE240

975-0163

LET 224

Page 2 - Josette Decaux

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

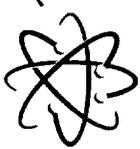
HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:9/22/98

reviewed verbally:GCF-1:Dorsey:9/22/98

f/t:HFS-456:rjm:9/22/98:docname:61277.adv:disc32



catalysis

Zurbano, 39
E - 28010 Madrid
ESPAÑA / SPAIN

Tel. +34 1 345 69 02
Fax. +34 1 345 97 25

Wlam

E-mail.:
www.catalysis.com

09/01/98

Office of Special Nutritionals
HFS 450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street, S.W.
Washington, D.C. 20204



Re: Notification Letter for Statements of Nutritional Support

Dear Sir or Madam:

1. **Statement of Purpose.** This notification letter is to provide notification of the following statement of nutritional support "DIAMEL provides the necessary nutrients that complement and enrich the diet of diabetic patients."
2. **Vendor Information.** Manufacturer: CATALYSIS, S.A.
Address: C/Zurbano, 39
28010 Madrid, Spain
Telephone: +34 1 345 69 02
3. **Product Identification.** Trade name: DIAMEL.
DIAMEL is a dietary supplement made of lettuce and oligoelements, specifically designed for diabetic patients.
4. **Ingredient Statement.** Arginine, glycine, fumaric acid, ascorbic acid, l-carnitine, ornithine, acetylcysteine, calcium pantotenate, pyridoxal, folic acid, cyanocobalamin, lettuce extract, blueberry extract, zinc sulfate, sodium methylparaben, cyclamate sodium and water.
5. **Intended Use.** The recommended dosage is two capsules before the three main meals of each day.
6. **Statements of Affirmation.** The information contained in this notice is complete and accurate and there is supporting evidence that the statement of nutritional support is truthful, not misleading and scientifically valid. Moreover, the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.

Respectfully submitted,

CATALYSIS, S.L.

By JOSETTE DECAUX, *President*